

**THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

C.A. No. 21-1015 (GBW)

**JURY TRIAL DEMANDED**



**DECLARATION OF AMY M. DUDASH IN SUPPORT OF NS'S  
MOTIONS FOR SUMMARY JUDGMENT AND DAUBERT MOTIONS**

I, Amy M. Dudash, hereby declare as follows:

1. I am an attorney at the law firm of Morgan, Lewis & Bockius LLP and counsel for Plaintiff Nippon Shinyaku Co., Ltd. and counter-claim Defendant NS Pharma, Inc. (collectively, “NS”) in the above-referenced matter and submit the instant declaration in support of NS’s Motions for Summary Judgment and *Daubert* Motions.

2. Attached as Exhibit 1 is a true and accurate copy of the Opening Expert Report of Steven F. Dowdy, Ph.D., dated September 7, 2023.

3. Attached as Exhibit 2 is a true and accurate copy of the Rebuttal Expert Report of Steven F. Dowdy, Ph.D., dated October 11, 2023.

4. Attached as Exhibit 3 is a true and accurate copy of the Reply Expert Report of Steven F. Dowdy, Ph.D., dated October 27, 2023.

5. Attached as Exhibit 4 is a true and accurate copy of the Opening Expert Report of Christine C. Esau, Ph.D., dated September 1, 2023.

6. Attached as Exhibit 5 is a true and accurate copy of the Expert Report of Dr. Michelle L. Hastings Regarding Invalidity of the UWA Patents, dated September 8, 2023.

7. Attached as Exhibit 6 is a true and accurate copy of the Responsive Expert Report of Dr. Michelle L. Hastings Regarding the Validity of the NS Patents, dated October 11, 2023.

8. Attached as Exhibit 7 is a true and accurate copy of the Reply Expert Report of Dr. Michelle L. Hastings Regarding the Invalidity of the UWA Patents, dated October 27, 2023.

9. Attached as Exhibit 8 is a true and accurate copy of the Expert Report of Andrew H. Hirshfeld, dated October 11, 2023.

10. Attached as Exhibit 9 is a true and accurate copy of the Expert Rebuttal Report of Andrew H. Hirshfeld, dated October 27, 2023.

11. Attached as Exhibit 10 is a true and accurate copy of the Rebuttal Expert Report of John C. Jarosz, dated October 11, 2023.

12. Attached as Exhibit 11 is a true and accurate copy of the Responsive Expert Report of Scott E. Kamholz, Esq., dated October 11, 2023.

13. Attached as Exhibit 12 is a true and accurate copy of the Opening Expert Report of Stanley Nelson, M.D., September 8, 2023.

14. Attached as Exhibit 13 is a true and accurate copy of excerpts of the November 8, 2023 deposition transcript of Steven F. Dowdy, Ph.D.

15. Attached as Exhibit 14 is a true and accurate copy of excerpts of the November 17, 2023 deposition transcript of Andrew H. Hirshfeld.

16. Attached as Exhibit 15 is a true and accurate copy of excerpts of the July 18, 2023 deposition transcript of Jurjus Jurayj.

17. Attached as Exhibit 16 is a true and accurate copy of excerpts of the July 27, 2023 deposition transcript of Amy Mandragouras.

18. Attached as Exhibit 17 is a true and accurate copy of excerpts from the May 3, 2023 *Markman* hearing transcript.

19. Attached as Exhibit 18 is a true and accurate copy of excerpts of the July 26, 2023 deposition transcript of Frederick Schnell, Ph.D.

20. Attached as Exhibit 19 is a true and accurate copy of excerpts of the June 26, 2023 deposition transcript of Naoki Watanabe.

21. Attached as Exhibit 20 is a true and accurate copy of excerpts of the June 27, 2023 deposition transcript of Naoki Watanabe.

22. Attached as Exhibit 21 is a true and accurate copy of the Appendix to First Supplemental Interrogatory 21 Response dated July 27, 2023.

23. Attached as Exhibit 22 is a true and accurate copy of the Nippon Shinyaku Co., Ltd., NS Pharma, Inc., and Sarepta Therapeutics, Inc.'s Joint Claim Construction Brief for the NS Patents, dated March 20, 2023 [D.I. 173].

24. Attached as Exhibit 23 is a true and accurate copy of the University of Western Australia Motion 1, Patent Interference No. 106,007.

25. Attached as Exhibit 24 is a true and accurate copy of the University of Western Australia Reply 1, Patent Interference No. 106,007.

26. Attached as Exhibit 25 is a true and accurate copy of the Nippon Shinyaku Co., Ltd., NS Pharma, Inc., and Sarepta Therapeutics, Inc.'s Joint Claim Construction Brief for the Wilton/UWA Patents, dated March 20, 2023 [D.I. 166].

27. Attached as Exhibit 26 is a true and accurate copy of Sarepta's Non-Infringement Contentions (including Exhibits A-1 to A-7, thereto), dated July 11, 2023.

28. Attached as Exhibit 27 is a true and accurate copy of Sarepta's Response to Interrogatory No. 21, dated August 15, 2023.

29. Attached as Exhibit 28 is a true and accurate copy of a document bearing Bates numbers NS00000477-NS00000826.

30. Attached as Exhibit 29 is a true and accurate copy of a document bearing Bates numbers SRPT-VYDS-0002984-SRPT-VYDS0005241.

31. Attached as Exhibit 30 is a true and accurate copy of a document bearing Bates numbers SRPT-VYDS-0213411-SRPT-VYDS-0213541

32. Attached as Exhibit 31 is a true and accurate copy of a document bearing Bates numbers SRPT-VYDS-0213508-SRPT-VYDS-0213541.

33. Attached as Exhibit 32 is a true and accurate copy of a document bearing Bates numbers SRPT-VYDS-0006978-SRPT-VYDS-0006990.

34. Attached as Exhibit 33 is a true and accurate copy of a document bearing Bates numbers SRPT-VYDS-0007014-SRPT-VYDS-0007015.

35. Attached as Exhibit 34 is a true and accurate copy of a document bearing Bates numbers SRPT-VYDS-0007043-SRPT-VYDS-0007047.

36. Attached as Exhibit 35 is a true and accurate copy of a document bearing Bates numbers SRPT-VYDS-0007049- SRPT-VYDS-0007050.

37. Attached as Exhibit 36 is a true and accurate copy of a document bearing Bates numbers SRPT-VYDS-0007051- SRPT-VYDS-0007088.

38. Attached as Exhibit 37 is a true and accurate copy of the Email from Ryan O'Quinn to Amanda Williamson, dated December 6, 2023.

Executed this 11th day of December, 2023.

/s/Amy M. Dudash  
Amy M. Dudash